UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,706	01/23/2006	Shing Yue Chan	CU60405	7430

20462 7590 02/08/2011

GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
02/08/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,706	CHAN ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *11-22,25-34 and 38-47* is/are withdrawn from consideration.

5)☒ Claim(s) *1-10,23-24, 35-37* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/20/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and IDS, both filed 04/20/2010; and response to a non-final office action filed 04/09/2010.

Claims 1-34 previously presented.

Claims 35-47 are currently added.

Claims 1-47 are pending.

Election/Restrictions

1. Newly submitted claims 38-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 38-42 are directed to distinct invention that does not require buffering agent. Claims 43-47 is directed to product by process, however, the product does not require buffering agent, and produced by non-elected process.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35, 38-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 11-22, 25-34 drawn to an invention nonelected with traverse in the reply filed on 09/24/2009, and non-elected claims by original presentation 38-47. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-10, 23, 24, and 35-37 are included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

3. The examiner acknowledges the amendment made to the specification. However, the examiner noted that "Eudragit NE 30" has been replaced by "EUDRAGIT® NE", and it is not clear to the examiner if "NE 30" and "NE" are the same trademarks having the same composition.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10, 23-24, 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0068376) in view of Lerner et al. (US 6,197,331), as evident by the article by Lamosa et al. ("Design of Microencapsulated Chitosan Microspheres for Colonic Drug Delivery"), all references are of record.

Applicant Claims

Applicants' claim 1 is directed to an orally dissolving film composition comprising:

a) an enteric polymer;

b) at least one alkaline buffering agent; and

c) at least one active agent.

Applicants' new claim 36 is directed to an orally dissolving film composition comprising:

a) a pre-neutralized poly(ethylacrylate -methacrylic acid) copolymer;

b) at least one alkaline buffering agent; and

c) at least one nicotine active agent selected from the group consisting of nicotine monotartrate, nicotine bitartrate, nicotine hydrochloride, nicotine dihydrochloride, nicotine sulfate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine oil, nicotine complexed with cyclodextrin, polymer resin, and mixtures thereof.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Chen teaches dosage form of nicotine delivery system in the form of mucoadhesive film that dissolve when applied intraorally to release nicotine which is absorbed through the oral mucosa to the systemic circulation. The mucoadhesive film is used to assist smoking cessation and for providing substitutes for smoking (abstract). The film comprises nicotine, buffering agents, polymer and plasticizer (paragraphs 0011, 0062). The film can be monolayer, or bilayer in which one layer contains nicotine

and the other layer contains buffering agent (paragraph 0012). The nicotine can be salts such as hydrochloride, dihydrochloride, sulfate, zinc chloride, or salicylate (paragraph 0014). The buffering agents include sodium carbonate or bicarbonate, and sodium and potassium phosphate (paragraph 0015). The polymer includes polyacrylic acid polymers (paragraph 0059).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Chen teaches mucoadhesive film and suggests polyacrylic acid polymers, however, the reference does not explicitly teach enteric polymers as claimed by claims 1 and 36. Chen does not teach nicotine oil as claimed by claim 8 and 37.

Lerner teaches composition in form of patch for applying pharmaceutical active agent to the oral cavity to release the agent for predetermined period at predetermined concentration for systemic or local action (abstract; col.7, lines 50-51). The composition provides oral release of pharmaceutical agent and buccal absorption resulting in rapid systemic delivery of the released pharmaceutical (col.7, lines 1-4). The composition is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged (col.7, lines 8-11, 18-19). The composition comprising pH buffering agent (col.11, lines 54-65), and polymer including neutral copolymer based on acrylic acid ester and methacrylic acid, with Eudragit L100 most preferred (col.11, lines 1-23; claim 4). Eudragit L 100 is enteric pH sensitive polymer as evident by Lamosa.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an oral dissolvable film comprising nicotine, buffering agent and polyacrylic polymer to release nicotine in the oral cavity as taught by Chen, and replace the polyacrylic acid polymer with enteric polymer, specially neutral copolymer of methacrylic acid and acrylic acid esters as taught by Lender. One would have been motivated to do so because Lender teaches that enteric polymers, specially neutral copolymer of methacrylic acid and acrylic acid esters are suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged, and further suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical. One would reasonably expect formulating oral dissolvable film comprising nicotine, buffering agent and enteric polymer to release nicotine in the oral cavity to be absorbed from the buccal mucosa to provide rapid systemic effect, and meanwhile the film is comfortable in the mouth of the user.

Regarding nicotine oil as claimed by claims 8 and 37 and nicotine polacrilex claimed by claim 35, applicants failed to show unexpected results obtained from nicotine oil and nicotine polacrilex over the use of nicotine salts disclosed by Chen et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

8. Claims 8, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Chen and Lender as evident by Lamosa and further in view of Adusumili et al. (US 2004/0037879), all references are of record.

The combined teachings of Chen and Lender as evident by Lamosa are previously discussed as set forth in this office action.

The references, however, do not teach nicotine oil in particular as claimed by claims 8 and 37 and nicotine polacrilex claimed by claim 35.

Adusumili teaches oral dosage formulations comprising nicotine active to alleviate some of the nicotine withdrawal symptoms that a person may experience during attempts to quit smoking (abstract). The nicotine active may be selected from a wide variety of nicotine sources such as pharmaceutically acceptable salts of nicotine. Non-limiting examples of such salts include nicotine monotartrate, bitartrate, hydrochloride, dihydrochloride, sulfate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine oil and nicotine polacrilex (paragraph 0032).

Adusumili teaches the equivalency between nicotine salts, nicotine oil and nicotine polacrilex in a process for alleviating nicotine withdrawal symptoms that a person may experience during attempts to quit smoking.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an oral dissolvable film comprising nicotine salts,

buffering agent and enteric polymer to assist smoking cessation as taught by the combination of Chen and Lender, and further replace nicotine salt with nicotine oil or nicotine polacrilex taught by Adusumili. One would have been motivated to do so because Adusumili teaches the equivalency between nicotine salts and nicotine oil in process for alleviating nicotine withdrawal symptoms. One would reasonably expect formulating an oral dissolvable film comprising nicotine oil or nicotine polacrilex, buffering agent and enteric polymer wherein the film assists to alleviate nicotine withdrawal symptoms that a person may experience during attempts to quit smoking.

Response to Arguments

9. Applicant's arguments filed 04/09/2010 have been fully considered but they are not persuasive.

Applicants argue that Adusumilli would not preclude patentability of claim 8 in view of 35 U.S.C. § 103(c). In particular, to the extent Adusumilli qualifies as prior art to the present application, it would be under 35 U.S.C. § 102(e) (Adusumilli published on February 26, 2004, after the July 24, 2003, priority date of the present application). Records indicate that both Adusumilli and the present application were under common ownership by SmithKline Beecham Corporation at the time the subject invention was made. The assignment for the present application is at Reel 017777, Frame 0420 and the assignment for Adusumilli is at Reel 013581 Frame 0852. Accordingly, Adusumilli is not available as prior art in accordance with 35 U.S.C. § 103(c).

In response to this argument, it is argued that Adusumili's publication (US 2004/0037879), by the same assignee of the present application is qualified as prior art because it has effective filing date 11/02/2001 and has different inventive entity. Further, Adusumili does not disclose the subject matter of the present invention directed to an orally dissolving film composition comprising: a) an enteric polymer; b) at least one alkaline buffering agent; and c) at least one active agent. See *In re Chu* (CAFC) 36 USPQ2d 1089 (1995).

Further, the examiner is pointing out to section 706.02(l)(2) [R-2] of MPEP regarding "Establishing Common Ownership" states that: "In order to be disqualified as prior art under 35 U.S.C. 103(c), **the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned at the time the claimed invention was made, or subject to an obligation of assignment that would establish common ownership.** The following statement is sufficient evidence to establish common ownership of, or an obligation for assignment to the same person(s) or organizations(s):

"Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person".

The statement concerning common ownership should be clear and conspicuous (e.g., on a separate piece of paper or in a separately labeled section) in order to ensure that the examiner quickly notices the statement. Applicants may, but are not required to, submit further evidence, such as assignment records, affidavits or declarations by the common owner, or court decisions, in addition to the above-mentioned statement concerning common ownership.

With respect to the combination of Chen with Lerner, applicants argue that Chen is directed to "an intraoral quick-dissolving film which is applied lingually. The dosage form is applied to the tongue.., and rapidly disintegrates, dissolves and releases nicotine." As recognized by the Action, Chen does not teach the use of enteric polymers for its film. Rather, the films in Chen comprise nicotine and a non-microbial hydrocolloid comprises water soluble and non-gelling natural gums or derivatives thereof, water soluble and non-gelling polypeptides, and water soluble synthetic polysaccharides. There is no suggestion in Chen that these water soluble components can or should be replaced with enteric polymers or that enteric polymers would produce the described quick-dissolving film. The quick-dissolving film of Chen provides for "a relatively rapid initial increase in blood nicotine concentration that simulates the pattern obtained by smoking a cigarette or taking a nasal spray."

In response to this argument, it is argued that the present claims are not directed to a any method of application of the orally dissolvable film, rather directed to a product that dissolve in the oral cavity. Applicants themselves admit Chen is directed to "an

intraoral quick-dissolving film which is applied lingually". Lingual and sublingual areas are part of the oral cavity. It is noted that the features upon which applicant relies (i.e., site of application and speed of dissolution of the film) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is further noted that Chen suggested using polyacrylic acid polymers in paragraph 0059, and those can be replaced by enteric polyacrylic acid polymers taught by Lerner because Lender teaches that enteric polymers, specially neutral copolymer of methacrylic acid and acrylic acid esters are suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged, and further suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical. Therefore, motivation to use enteric polymers is oral dissolvable formulation is taught by Lerner and reasonable expectation to arrive to the present invention exists.

Regarding applicant's argument concerning rapid-dissolution of the film taught by Chen, it is noted that applicants' claims do not recite any dissolution time of the film. The film taught by Chen is used for the same purpose as instantly claimed film.

Applicants argue that Lerner is directed to an oral patch that "adheres to hard dental surfaces, such as teeth and dentures." The oral patch is designed to remain on

the tooth or denture for a period of time and provide controlled or sustained release of pharmaceutical agents to the patent. Although Lerner refers to certain Eudragit® polymers as suitable polymers for release layers and/or adhesive layers, there is no discussion of these polymers imparting "quick dissolving" characteristics on the oral patch. This lack of teaching is consistent with the understanding of one skilled in the art with respect to enteric coatings that are useful for delayed release of an active agent until a particular dosage form reaches the intestine. Lerner further distinguishes itself from quick dissolving films, like those disclosed in Chen. Lerner states that a significant advantage of its "oral patch" over films is that the oral patch provides for greater adhesion than films, resulting in treatment for longer periods of time.

In response to this argument, it is argued that oral patch taught by Lerner reads on the present claimed orally dissolvable film, in absence of claiming any specific site of application. Lerner is relied upon, as applicants' admit, for teaching specific neutral copolymer of methacrylic acid and acrylic acid esters. Lerner teaches such polymer as being suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged. Lerner teaches that such polymers are **suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical**. Sustained release patch as taught by Lerner does not prevent rapid onset of action of the released drugs in the oral cavity because of the nature of the mucosa and its rich blood supply, therefore the ultimate result obtained from Chen which is rapid action of the drug is also desired by Lerner,

which is rapid delivery. There is motivation to replace the polyacrylic acid polymer of Chen with those of Lerner as well as reasonable expectation to arrive to the present invention as previously discussed. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants argue that when both references are viewed in their entirety, one skilled in the art would not be motivated to combine the film of Chen with the polymers of Lerner. Whereas Chen is directed to a film comprising water-soluble polymers that is applied to the tongue and quickly dissolves to release nicotine, Lerner is directed to a patch that adheres to a tooth or denture and provides for a controlled or sustained release of a pharmaceutical agent. This is emphasized in view of Lerner's teachings about its benefits over "films" and the understanding of those skilled in the art with respect to the dissolution characteristics of the enteric polymers disclosed in Lerner.

In response to this argument, it is repeated that Lerner teaches neutral polymers as **suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical**. Sustained release patch as taught by Lerner does not prevent rapid onset of action of the released drugs in the oral cavity because of the nature of the mucosa and its rich blood supply, therefore the ultimate result obtained from Chen which is rapid action of the drug is also desired by Lerner, which is rapid delivery.

The examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an oral dissolvable film comprising nicotine, buffering agent and polyacrylic polymer to release nicotine in the oral cavity as taught by Chen, and replace the polyacrylic acid polymer with enteric polymer, specially neutral copolymer of methacrylic acid and acrylic acid esters as taught by Lender. One would have been motivated to do so because Lender teaches that enteric polymers, specially neutral copolymer of methacrylic acid and acrylic acid esters are suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged, and further suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical. One would reasonably expect formulating oral dissolvable film comprising nicotine, buffering agent and enteric polymer to release nicotine in the oral cavity to be absorbed from the buccal mucosa to provide rapid systemic effect, and meanwhile the film is comfortable in the mouth of the user. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion

of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re kerkhoven* 205 USPQ 1069, 1072. In the instant case combination for forming orally administered film to deliver nicotine. In ant event, it has been decided by the Courts that even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions. In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design

community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicants argue that even if one were to combine Chen with Lerner, they would not arrive at the claimed invention of claim 3. Neither of the references teaches an orally dissolving film composition comprising a pre-neutralized, enteric polymer. Chen does not teach the use of enteric polymers and although Lerner does mention the use of enteric polymers, it does not teach the use of pre-neutralized enteric polymers.

In response to this argument, it is argued that, as applicants themselves admit, Lerner teaches neutral enteric polymers and teaches the same trademark Eudragit

L100 that is used by applicants. Eudragit L100 is neutral polymer which means has undergone neutralization, or in other words pre-neutralized. The prior art in combination teaches Eudragit and alkaline buffering agent which would inevitably produce pre-neutralized polymer.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611